

PSJ4 SOL Opp Exh 38

Message

From: Howenstein, Kim [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=KIM.HOWENSTEIN]
Sent: 4/28/2014 5:17:19 PM
To: Anna-Soisson, Kimberly [/O=CAH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Kimberly.anna-soisson]
Subject: FW: assistance
Attachments: DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS.docx; QRA SOM Customer Analytics.docx

This is should be a good start.
The first attachment is an SOP
The second attachment is working guidelines.

From: Mayeski, Ullrich
Sent: Monday, April 28, 2014 12:18 PM
To: Howenstein, Kim; Anna-Soisson, Kimberly
Subject: assistance

Happy Monday:

I need some help. I am meeting with all of the compliance officers next week here in Dublin. There are several topics that I have to address. One of them is how the compliance officers would facilitate an overview conversation about the SOM program during a DEA cyclic inspection. Can the two of you create a 6-7 slide presentation that addresses an overview of our program. This is something the compliance officers would share with DEA on-site and walk through with them during the inspection? The COs have a basic understanding about SOM, but this should be fairly hi level addressing basic components, particularly what happens when a threshold hits and cutting/reporting.

Oh and I need it by Thursday. You are the best!!



Ullrich C. Mayeski
Director of Investigations
Quality & Regulatory Affairs
7000 Cardinal Place, Dublin, OH 43017
614.757.7544



Standard Operating Procedure Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide guidance to Cardinal Health employees in the Quality and Regulatory Affairs (QRA) department on responding, detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about adjusting thresholds, releasing orders, or cutting orders.

It is also the purpose of this SOP to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which Drug Enforcement Administration (DEA) holds distributors responsible.

2.0 SCOPE

This SOP applies when an order is triggered by the Cardinal Health Anti-Diversion Centralization (or equivalent) system for evaluation so as to meet the purpose of the SOP mentioned in §1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

PDQRA-CAD-C008	On-Site QRA and Surveillance Investigations
fda.gov/regulatoryinformation/legislation/ucm148726.htm	Controlled Substances Act
deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm	21 CFR 1301.74(b)

4.0 RESPONSIBILITIES

The responsibilities of QRA includes

- a. Evaluating threshold events
- b. Identifying suspicious orders
- c. Reporting suspicious orders to DEA
- d. Performing a review of suspicious orders
- e. Making decisions regarding threshold adjustments
- f. Cutting suspicious orders when appropriate
- g. Releasing portions of orders when appropriate

5.0 DEFINITIONS

*Anti-Diversion
Centralization (ADC)
System*

Case management system used to facilitate the evaluation and assessment of threshold events, which are orders for controlled substance products held by the Suspicious Order Monitoring (SOM) electronic monitoring program. The case management system also allows members of Quality and Regulatory Affairs to reference customer specific information, as well as make adjustments to threshold limits and restrict customers from purchasing controlled substances.

Threshold

The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event

An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

6.0 PROCEDURE

6.1 Initial Review

6.1.1

The following orders are held or cut pending review by QRA under this procedure

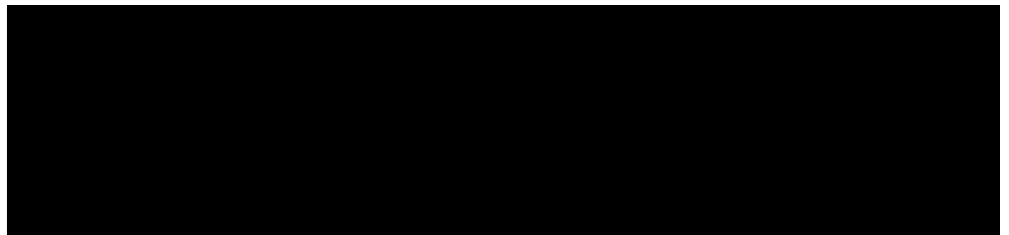
- a. Orders of interest referred to by a Forward Distribution Center
- b. Orders that exceed a threshold set for the customer for the drug family
- c. Orders that exceed any other criteria established by QRA



Standard Operating Procedure Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

- 6.1.2** In addition, under this SOP, QRA can review other orders that may come to the attention of QRA based on any other criteria.
- 6.1.3** Under this procedure, QRA must first review every held order under §6.1.1 to determine whether the order is suspicious as that term is used in 21 CFR. 1301.74(b). Per the regulation, orders are deemed suspicious if they meet one (1) or more of three (3) criteria:
- a. Order is of unusual size
 - b. Order is of unusual frequency
 - c. Order deviates substantially from a normal pattern for the customer
- 6.1.4** Orders that meet one or more of the criteria in §6.1.3 must be reported to the DEA as suspicious.
- 6.1.5** **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.
- 6.1.5.1** Orders of unusual size can be as a result of:
- a. Unintentional order entry errors (including duplicate order entries)
 - b. Intentional orders placed by the customer
- QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.
- 6.1.5.2** Unintentional order entry errors (including duplicate order entries) must be cut and reported to the DEA as suspicious, with no changes to customer threshold.
- 6.1.5.3** QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is cut and reported to the DEA as suspicious.
- 6.1.6** **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.
- 6.1.6.1** QRA personnel can use available information on order history and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order is of unusual frequency.
- 6.1.6.2** If QRA personnel determines the order to be of unusual frequency then the order is cut and reported to the DEA as suspicious.
- 6.1.7** **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.
- 6.1.7.1** Substantial deviations in ordering patterns include, but are not limited to,





Standard Operating Procedure Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

d. Other deviations based on QRA personnel's experience.

- 6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.
- 6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is cut and reported to the DEA as suspicious.

6.2 Review of Suspicious Orders

- 6.2.1 A held order that warrants an assessment is reviewed as described in written procedures to determine whether a threshold adjustment to the particular drug family is warranted.
 - 6.2.1.1 When the QRA personnel determines that a threshold adjustment is warranted because the personnel has found that the drugs are unlikely to be diverted, the personnel must ensure that the reasons for adjusting the threshold and relevant information considered have been recorded prior to adjusting the threshold.
 - 6.2.1.2 When the QRA personnel is unable to determine with information available that the order is not likely to be diverted, the current order and subsequent orders in the same drug family, above threshold, are cut, when appropriate, and reviewed on an individual basis to determine if a site visit is warranted.
- 6.2.2 **Selection of a suitable type of site visit** (refer to PDQRA-CAD-C008 for conducting site visits).
 - 6.2.2.1 The site visit type is determined by QRA personnel following written procedures.
- 6.2.3 **Decision based on findings of the site visit**
 - 6.2.3.1 If the decision is to suspend the customer, the current order and subsequent orders in the same drug family are cancelled and the threshold is set at one (1).
 - 6.2.3.2 If the decision is to retain the customer, the QRA personnel must:
 - a. Continue to monitor the customer; and
 - b. Determine if the customer's threshold levels should be considered for adjustment and make adjustments if necessary following written procedures.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

- 7.1.1 Not applicable.

7.2 Documentation Retention

- 7.2.1 Not applicable.



Standard Operating Procedure Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

Approvals

Approvals on file in the Pharmaceutical Distribution Corporate Document Center

Approvers: Todd Cameron

Owner:

Danielle Holbrook

PDCDC Coordinator:

Jason Paul Snouffer

Change History

DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3310	18 Jul 2013	Modify	Yes	Corporate	PDQRA - Analytics and SOM Compliance PDQRA - Pharmacy Assessment

Other (specify)

N/A

Change Description and Justification

Review process for held orders has been enhanced and updated.; Document Approver was updated from Nicholas Rausch to Todd Cameron.

QRA SOM Customer Analytics General Work Instructions

Scope

These general guidelines are limited to Retail Independent and Retail Chain customers ordering controlled substances through the core pharmaceutical distribution business¹, as well as the thirteen drug families² designated as having a high risk for abuse and diversion. These guidelines apply to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer threshold limits for the aforementioned customers and drug families.

Effective Date

January 15, 2013

Statement

Cardinal Health's QRA department will have a standardized method to assess and adjust threshold limits utilized within the electronic monitoring system of the Suspicious Order Monitoring (SOM) program.

For purposes of these guidelines, the assessment and adjustment process is outlined from initiation to conclusion. The initiation of an assessment could result from an early dialogue notice, held order, or proactive communication from the customer or sales department. The assessment could conclude with no change of a threshold limit, an increase or decrease of a threshold limit, resolution of a held order, and/or the report of a suspicious order to DEA.

The following outlines the sequence of steps and corresponding decisions that should generally occur for each type of assessment.

1.

2.

¹ Core pharmaceutical distribution business includes customers serviced by the 20 forward distribution centers.

² See Appendix 1 for the List of 13 Drug Families.

- [illegible]

- § 87(2)(b) [REDACTED]

⁴ See Appendix 2 for Customer Segmentation and Review Policies.

U.S. adults

Response	Percentage
Take more action	81%
Take some action	14%
Not necessary	3%
Don't know	2%

U.S. adults who are Democrats/lean Democrats

Response	Percentage
Take more action	87%
Take some action	9%
Not necessary	2%
Don't know	2%

1. [REDACTED]

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

CAH_MD L2804_00012251

[illegible]

Page 5

[illegible]

5. Empirical Assessment: [REDACTED]

[illegible]

⁷ See Appendix 4 for National Accounts Contact List.

⁸ See Appendix 5 for Customer Release Percentage.

¹¹ See Appendix 7 for Distribution Center Pharmacists Assignments.

Last Updated on September 20, 2013

¹⁶ See Appendix 2 for Customer Segmentation and Review Policies.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁷ See Appendix 8 for Secondary Customer Threshold Limits.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁸ See Appendix 9 for Non-Top 13 Drug Family Threshold Change Guidance.

APPENDIX

Appendix 1

Table 1: List of 13 Drug Families

[illegible]

Appendix 2

Table 2: Customer Segmentation and Review Responsibilities

[illegible]

Appendix 3

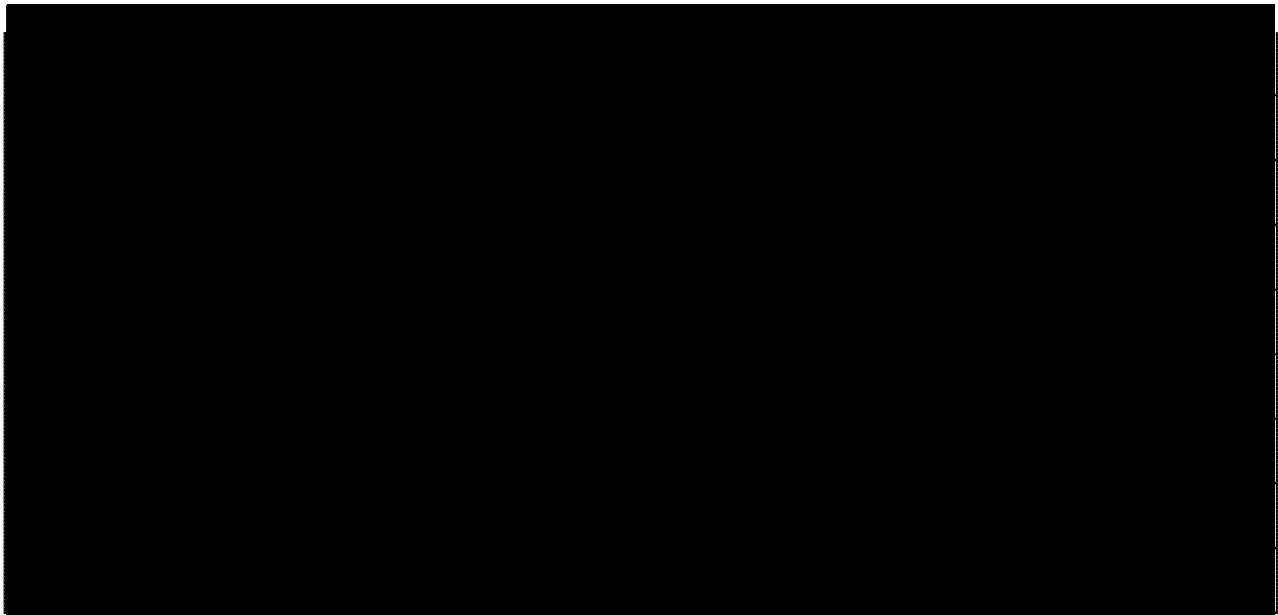
Table 3: Objective Criteria & Score Model

Criteria	Percent Within	Floor Dosage Units	Percentage		Score Reference			
			Floor	Cap	3	4	5	12

Appendix 4

Table 4: National Accounts Contact List

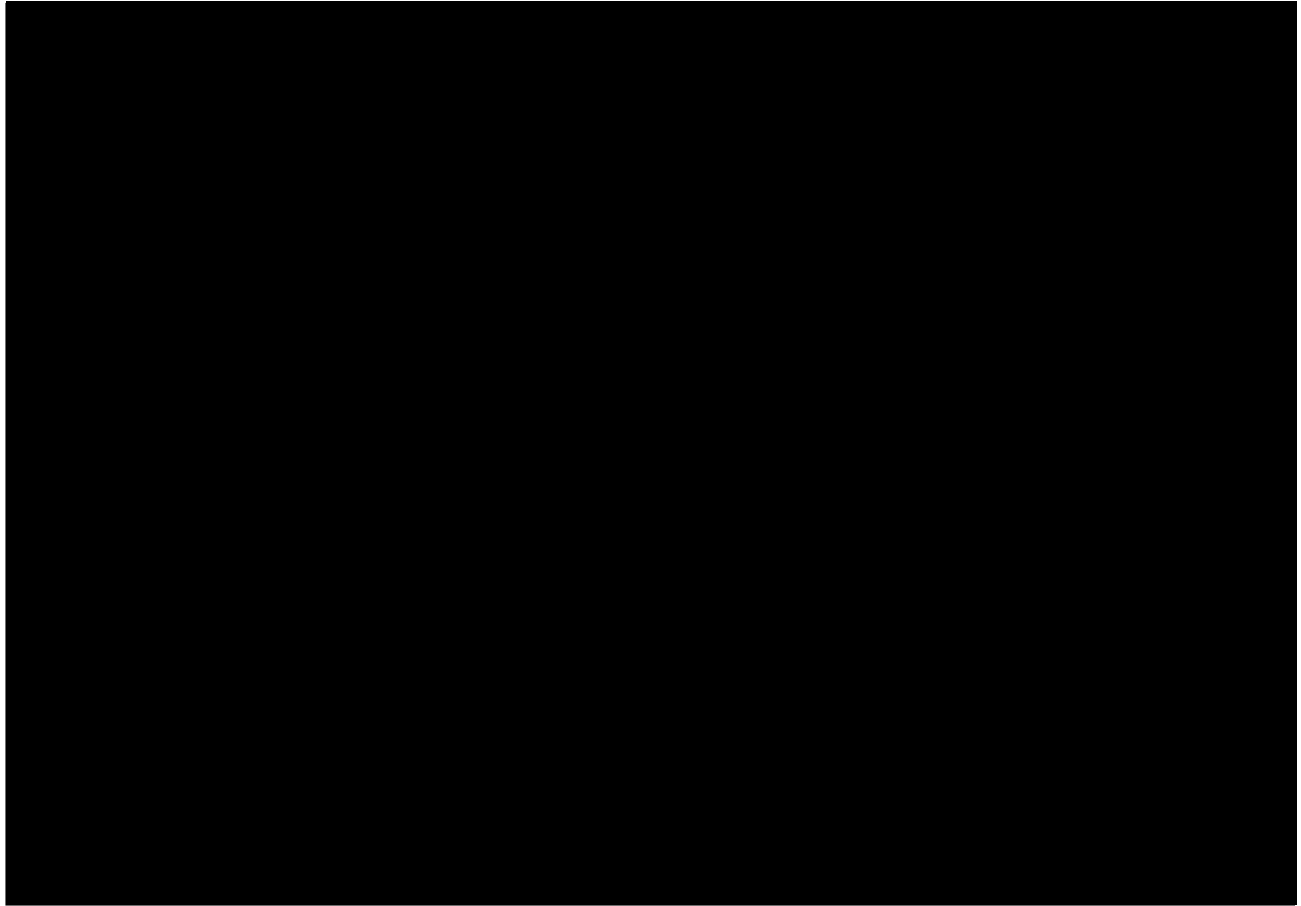
Customer Name	National Markets Sales



Appendix 5

Table 5: Customer Release Percentage

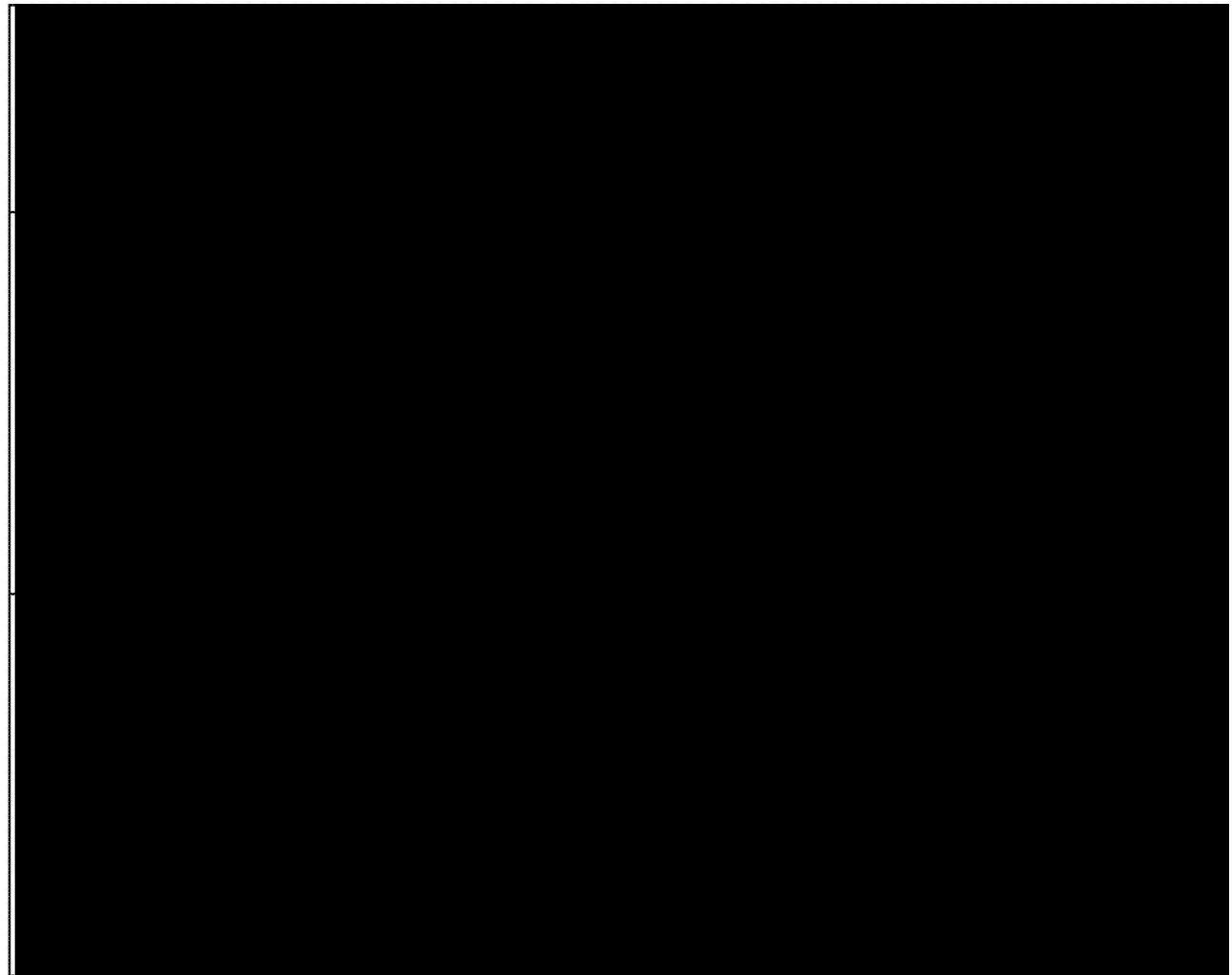
Threshold Limit	Allowable Percentage Over Threshold per Drug Family per Accrual Period	Example



Appendix 6

Table 6: Cardinal Health Distribution Position

National Chain Account	Primary Position	Secondary Position
[Redacted Table Content]		



Appendix 7

Table 7: Distribution Center Pharmacists Assignments

Distribution Center	DC#	Accrual Cycle End Date
Pharmacist – Janet Ng		

Pharmacist – Kimberly Anna-Soisson		
Pharmacist- Doug Emma		
Pharmacist – William Brady		
Pharmacist – Christopher Forst		

Appendix 8

Table 8: Secondary Customer Threshold Limits

Base Code	Description	Limit
[REDACTED]		

Appendix 9

Table 9: Non-Top 13 Drug Family Threshold Change Guidance

Category	Authority to Set Limit Danni's Team	2-Person Review (Pharmacist)	2-Person Review (VP)
[REDACTED]			